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## 8. 510 (k) Summary

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### Product Name:

Proprietary Name:	Perfecta™ Pregnancy Test
Common Name:	OTC Pregnancy Test Kit
Classification Name:	Kit, Test, Pregnancy, HCG, OTC
Classification Number:	75LCX

Intended Use: Perfecta Pregnancy Test is a pregnancy test intended for home use.

Description: Perfecta Pregnancy Test uses color immunochromatographic technology with antibodies coated on the membrane. If hCG is present in urine, a blue test line will appear to indicate a positive result.

### Substantial Equivalence:

Perfecta Pregnancy Test is substantially equivalent to Abbott TestPack Plus hCG Urine Test, Warner-Lambert e.p.t Pregnancy Test and Carter Wallace FIRST RESPONSE Pregnancy Test. All these tests utilize immunochromatographic technology and anti-hCG antibodies to detect hCG in urine. All three tests interpret the results through the development of the color lines.

Applicant Signed: Shu-Ching Cheng Date: 1/14/97  
Shu-Ching Cheng